APR - 8 2011

K110479

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510(K) SUMMARY

Date Prepared: February 16, 2011

Submitted By:
Boston Scientific Corporation
Cardiac Rhythm Management
4100 Hamline Avenue North
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Contact Person:
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Trade Name: ACUITY Whisper View™ GUIDE WIRES
Common Name: Guide Wire
Classification: Class II, 21 CFR 870.1330
Product Code: DQX

Predicate Devices: Guidant HI-TORQUE Whisper View™ Guide Wire (K061453, cleared 06/22/2006)

Boston Scientific ACUITY™ Mailman™ (Model 7081) and ACUITY Strait-Trak™ (Model 7082) Venous Guide wires (K090554, cleared 07/2/2009)

Device Description: The ACUITY Whisper View guide wire family comprises three individual guide wires with different support profiles: Extra Support (ES), Distal Support (DS), and Extra Distal Support (EDS). The guide wires have a nominal diameter of 0.014 inches (0.36 mm) and a length of 190 centimeters, and are available with a straight distal tip that is shapeable or a preformed coronary sinus (CS) J-shaped tip. The guide wire is coated with a hydrophilic coating for increased lubricity.

The ACUITY Whisper View guide wires are available in the following models, rail supports, and tip shapes:

- Model 4640, Extra Support (ES), Straight
- Model 4641, Extra Support (ES), CS-J
- Model 4642, Distal Support (DS), Straight

- Model 4643, Distal Support (DS), CS-J
- Model 4647, Extra Distal Support (EDS), Straight
- Model 4648, Extra Distal Support (EDS), CS-J

Intended Use of the Device:

Boston Scientific ACUITY Whisper View™ Guide Wires with Hydrophilic Coating are intended to facilitate the placement of Boston Scientific or Guidant Left Ventricular (LV) leads within the coronary venous vasculature.

Technological Characteristics:

Similarities: Both the ACUITY Whisper View and the predicate HI-TORQUE Whisper View guide wires use a stainless steel core wire in the same lengths, guide wire support and shape options. The distal end of each device is radiopaque and can be seen under fluoroscopy for device placement. Both devices are highly lubricious for smooth delivery of therapeutic devices. The ACUITY Whisper View guide wire has the same intended use, same operating principle, similar design, uses similar materials, and has a similar performance.

Differences: The ACUITY Whisper View guide wires differ from the predicate HI-TORQUE Whisper View in the following aspects: design and material changes to the distal tip coil, radiopaque polymer jacket material, and hydrophilic coating. The ACUITY Whisper View guide wire uses the same radiopaque polymer jacket material and hydrophilic coating as used on Boston Scientific's ACUITY™ Mailman™ and ACUITY Strait-Trak™ guide wires (K061453).

Non-Clinical Test Summary:

Design verification testing, including mechanical bench testing, and design validation animal testing, were conducted to verify that the performance of the ACUITY Whisper View guide wires are substantially equivalent to the predicate devices. Biocompatibility, packaging/shelf life, and sterility testing were also completed.

Test results confirm that Boston Scientific ACUITY Whisper View guide wires meet all of the minimum requirements and are adequate for their intended use.

Clinical Test Summary:

Clinical evaluation was not required.

Statement of Substantial Equivalence:

The Boston Scientific ACUITY Whisper View guide wires are substantially equivalent to the predicate Guidant HI-TORQUE Whisper View guide wires based on a comparision of intended use, design, and the results of the testing and evaluation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Kirstin Johnston
Regulatory Affairs Specialist
Boston Scientific Corp.
4100 Hamline Ave, North
St. Paul, MN 55112

APR - 8 2011

Re: K110479
Trade/Device Name: ACUITY Whisper View Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: II (two)
Product Code: DQX
Dated: March 23, 2011
Received: March 24, 2011

Dear Ms. Johnston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K110479

Device Name: ACUITY WHISPER VIEW™ GUIDE WIRE

Indications For Use: Boston Scientific ACUITY WHISPER VIEW™ Guide Wires with Hydrophilic Coating are intended to facilitate the placement of Boston Scientific or Guidant Left Ventricular (LV) leads within the coronary venous vasculature.

Prescription Use [X] AND/OR Over-The-Counter Use [ ]

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110479